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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,746	02/20/2002	Antonio Facchiano	2507-1003	3449

466 7590 12/01/2004

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EXAMINER	
SNEDDEN, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,746	FACCHIANO ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *5-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of invention I, claims 1-4 is acknowledged. Claims 5-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's election with traverse in the reply filed on 10/27/2004 is acknowledged. The traversal is on the ground(s) that a search of the entire application may be performed without a serious search burden. This is not found persuasive because as the claims are directed to distinct inventions related as product and methods of using, in which a search for one invention would not include the search for the other. The requirement is still deemed proper and is therefore made FINAL. Claims 1-4 are under examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2- 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2-4 are directed to a genus of peptides homologous to the peptide of SEQ ID NO: 1 with respect to several physical or structural properties such as sequence homology, electric-charge homology or functional group disposition, for example. The specification

discloses the sequence SEQ ID NO: 1 and concepts regarding the meaning of "percent" (%), however, there is no description of functional differences brought about by a percent similarity difference (e.q., if there is a similarity difference of 73, 86 or 92%) that would result in a biologically active protein possessing a desired function. Thus, no relationship between the structural properties and functional properties is established. Furthermore, claims 3 and 4 recite properties of the peptide sequence of SEQ ID NO: 1 that is not supported in the specification. No guidance is provided as to what electric–charge homology, hydrophilia, hydrophobicity, solvent-exposure rate, or functional group disposition .

Therefore, only isolated peptides comprising the amino acid sequence set forth in SEQ ID NOs: 1, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Baird *et al.* (US 5,252,718). Baird *et al.* teaches a peptide that comprises a sequence 100% identical to SEQ ID NO: 1 (See Example 1, bFGF from amino acid 25-35, for example; see also attached sequence alignment)(Note: "having" as recited in the claim is interpreted as "comprising"). The peptide of Baird *et al.* would thus comprise all of the properties, such as electric-charge homology or

conformation similarity, inherent to the amino acid sequence of SEQ ID NO: 1. Thus, the reference clearly anticipates the invention as recited in the claims.

Conclusion

4. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
November 29, 2004
SKS

JON WEBER
SUPERVISORY PATENT EXAMINER

CC diagnostically or therapeutically, eg to treat proliferative diseases of
CC eyes and kidneys, some types of tumours and adrenal vascularisation. It
CC is able to bind with heparin or with the FGF receptor. See also AAP71542,
CC AAP71557, AAP71558 and AAP71561. (Updated on 25-MAR-2003 to correct PA
CC field.)
XX
SQ Sequence 45 AA;

Query Match 100.0%; Score 57; DB 1; Length 45;
Best Local Similarity 100.0%; Pred. No. 0.0022;
Matches 11; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 DPHIKLQLQAE 11
||||||||||
Db 25 DPHIKLQLQAE 35

RESULT 14
AAR43278
ID AAR43278 standard; peptide; 45 AA.
XX
AC AAR43278;
XX
DT 25-MAR-2003 (revised)
DT 05-MAY-1994 (first entry)
XX
DE FGF antagonist bFGF(24-68)-NH2.
XX
KW Bovine; basic fibroblast growth factor; antagonist; mitogen; melanoma;
KW glomerulonephritis; retinopathy.
XX
OS Synthetic.
XX
FH Key Location/Qualifiers
FT Modified-site 45
FT /note= "amidated"
XX
PN US5252718-A.
XX
PD 12-OCT-1993.
XX
PF 27-APR-1992; 92US-00873773.
XX
PR 22-APR-1986; 86US-00854843.
PR 14-NOV-1988; 88US-00270225.
XX
PA (SALK) SALK INST BIOLOGICAL STUDIES.
XX
PI Baird JA, Ling NC;
XX
DR WPI; 1993-336156/42.
XX
PT New fibroblast growth factor peptide(s) - are FGF antagonists used to
PT inhibit cell growth in culture or in disease e.g. retinopathy,
PT glomerulonephritis, melanoma etc.
XX
PS Example 1; Col 10; 12pp; English.
XX
CC The peptide bFGF(24-68)-NH2 (100mcg/ml) reduces the amount of radioactive
CC bFGF bound to the BHK cells by 54% and shows strong affinity to bind
CC heparin. (Updated on 25-MAR-2003 to correct PF field.)
XX
SQ Sequence 45 AA;

Query Match 100.0%; Score 57; DB 2; Length 45;
Best Local Similarity 100.0%; Pred. No. 0.0022;
Matches 11; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 DPHIKLQLQAE 11
||||||||||
Db 25 DPHIKLQLQAE 35

RESULT 15
AAB18551
ID AAB18551 standard; peptide; 45 AA.
XX
AC AAB18551;
XX
DT 15-JAN-2001 (first entry)
XX
DE Immunogenic peptide fragment derived from FGF and/or VEGF.
XX
KW Immunogenic peptide; fibroblast growth factor; FGF; VEGF; cancer;
KW vascular endothelial growth factor; hyperproliferative disorder;
KW haemangioma; solid tumour; blood borne tumour; leukaemia; metastasis;
KW telangiectasia; psoriasis; scleroderma; pyogenic granuloma;
KW myocardial angiogenesis; Crohn's disease; plaque neovascularisation;
KW arteriovenous malformation; corneal disease; rubeosis;
KW neovascular glaucoma; diabetic retinopathy; retrolental fibroplasia;
KW arthritis; diabetic neovascularisation; macular degeneration;
KW wound healing; peptic ulcer; Helicobacter related disease; fracture;
KW keloid; vasculogenesis; hematopoiesis; ovulation; menstruation;
KW placentation; cat scratch fever.
XX
OS Unidentified.
XX
PN WO200053219-A2.
XX
PD 14-SEP-2000.
XX
PF 10-MAR-2000; 2000WO-US006320.
XX
PR 11-MAR-1999; 99US-00266543.
XX
PA (ENTR-) ENTREMED INC.
XX
PI Holaday JW, Ruiz A, Madsen J;
XX
DR WPI; 2000-594263/56.
XX
PT An immunogenic composition useful for treating cancer or
PT hyperproliferative disorders comprises an immunogenic peptide fragment of
PT fibroblast growth factor and/or vascular endothelial growth factor.
XX
PS Disclosure; Page 28; 95pp; English.
XX
CC AAB18542-51 represent immunogenic peptide fragments of fibroblast growth
CC factor (FGF) and/or vascular endothelial growth factor (VEGF). The
CC peptides are used to produce immunogenic compositions. The immunogenic
CC composition is used for treating cancer or hyperproliferative disorders,
CC especially haemangioma, solid tumours, blood borne tumours, leukaemia,
CC metastasis, telangiectasia, psoriasis, scleroderma, pyogenic granuloma,
CC myocardial angiogenesis, Crohn's disease, plaque neovascularisation,
CC arteriovenous malformations, corneal diseases, rubeosis, neovascular
CC glaucoma, diabetic retinopathy, retrolental fibroplasia, arthritis,
CC diabetic neovascularisation, macular degeneration, wound healing, peptic
CC ulcer, Helicobacter related diseases, fractures, keloids, vasculogenesis,
CC hematopoiesis, ovulation, menstruation, placentation and cat scratch
CC fever
XX
SQ Sequence 45 AA;

Query Match 100.0%; Score 57; DB 3; Length 45;
Best Local Similarity 100.0%; Pred. No. 0.0022;
Matches 11; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 DPHIKLQLQAE 11
||||||||||
Db 25 DPHIKLQLQAE 35

Search completed: November 17, 2004, 01:38:23
Job time : 157 secs

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